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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,202	09/26/2001	Paula N. Belloni	9080-011-999	5269

7590                    03/17/2003

PENNIE & EDMONDS, LLP  
1155 Avenue of the Americas  
New York, NY 10036-2711

[REDACTED] EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
1616	[REDACTED]

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/966,202	BELLONI, PAULA N.
	<b>Examiner</b>	<b>Art Unit</b>
	Konata M. George	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 January 2003.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 6-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 6-47 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>7</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____   |

## DETAILED ACTION

Claims 1 and 6-47 are pending in this application.

### ***Action Summary***

1. Examiner acknowledges the cancellation of claims 2-5.
2. The objection of claim 23 as being of improper dependent form is hereby withdrawn.
3. The rejection of claims 1-10, 21, 22 and 24-34 under obviousness-type doubling patenting over claims 1-22 of U.S. Patent No. 6,339,107 B1 is hereby withdrawn as a timely filed terminal disclaimer was filed.
4. The rejection of claims 11-20 and 35 under 35 U.S.C. 103(a) over Bollag et al. is hereby withdrawn.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 11-20 and 35 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 and 6-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tong et al. (US 6,515,022 B2).

Art Unit: 1616

Tong discloses the use of inhaled retinoids in the treatment of lung diseases.

Column 2, lines 14-17 describes that retinoid therapy can be used for treatment and prevention of various lung diseases including emphysema also note claim 9. The retinoids of choice can include all of the "natural retinoids" such as all-trans retinoic acid, 13-cis and 9-cis retinoic acids (col. 4, lines 15-20). One aspect of the invention is a solution comprising a retinoid, a chlorofluorocarbon solvent and an alkylamine (col. 4, lines 7-11). The dosage amount of the retinoid is from 50 to 500 µg (col. 4, lines 25-28). Several dosage forms are characterized in the prior art such as metered dosage and dry powders inhaler (col. 4, lines 25-28 and 56-65). The prior art does not teach a method of treating different types of emphysema.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use of the composition and method of Tong for the treatment of the different types of emphysema. It is the position of the examiner that emphysema as used by Tong is used to describe the broad category of the disease and that panlobar emphysema, centrilobular emphysema, etc. fall under this broad category and are thus disclosed in Tong.

Applicant argues that 13-cis has a therapeutic profile substantially superior to that of ATRA (page 6, lines 14-17). Further, example 6 is cited to show this comparison of 13-cis with ATRA. One skilled in the art would expect the 13-cis isomer to have different pharmacokinetic profile than the racemic mixture (page 10, lines 25-34) and therefore different results. The finding that 13-cis is more favorable compared to ATRA is not unexpected. Further, Tong et al. specifically teaches using 13-cis retinoic acids.

***Specification***

7. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate subject matter into this application by reference to EP 959069, WO 99/48866, EP 742204, WO 97/39745, WO 94/12285, WO 94/14543, WO 95/26234, WO 95/26235 and WO 95/32807 is improper because it contains essential subject matter to which the application depends from foreign patents and publications.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

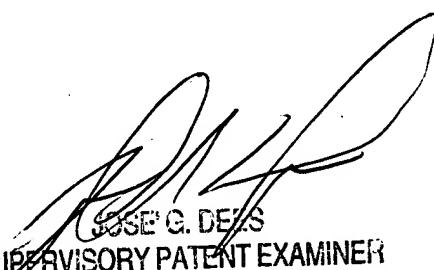
***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

  
JOSÉ G. DEES  
SUPERVISORY PATENT EXAMINER

1616